

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

JANSSEN BIOTECH, INC. and
NEW YORK UNIVERSITY

Plaintiffs,

vs.

CELLTRION HEALTHCARE CO., LTD.,
CELLTRION, INC., and
HOSPIRA, INC.

Defendants.

Civil Action No. 1:15-cv-10698

STIPULATION OF VOLUNTARY DISMISSAL UNDER FED. R. CIV. P. 41(a)(1)

WHEREAS, Defendant Celltrion, Inc. submitted an abbreviated Biologic License Application (“aBLA”) No. 125544 seeking permission to market a proposed biosimilar version of Plaintiff Janssen Biotech, Inc.’s (“Janssen”) biological medicine Remicade (infliximab);

WHEREAS, Janssen has sued Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc. (collectively, “Defendants”) in count 5 of the complaint for infringement of U.S. Patent No. 5,807,715 (the ““715 patent”) under 35 U.S.C. § 271(e)(2)(C)(i) based on the submission of aBLA No. 125544 for marketing approval of Defendants’ proposed infliximab biosimilar products;

WHEREAS, Janssen has sued Defendants in count 7 of the complaint for infringement of U.S. Patent No. 6,900,056 (the ““056 patent”) under 35 U.S.C. § 271(e)(2)(C)(ii) based on the submission of aBLA No. 125544 and Defendants’ alleged failure to provide manufacturing information in addition to the aBLA itself under the Biologics and Price Competition and Innovation Act (“BPCIA”);

WHEREAS, Defendants have answered the complaint and have asserted defenses that pertain to the '715 and '056 patents;

WHEREAS, the '715 patent expired on September 15, 2015, and Defendants have agreed that they will not launch any biosimilar infliximab product in the United States until after September 15, 2015; and

WHEREAS, Defendants' third-party supplier of cell growth media provided a spreadsheet on May 28, 2015 describing the cell growth media used for Defendants' proposed infliximab biosimilar products subject to the aBLA ("Cell Growth Media Spreadsheet"). *See* spreadsheet attached as Exhibit A (sealed).

NOW THEREFORE, IT IS HEREBY STIPULATED, AGREED, AND ORDERED that:

1. Defendants will not launch any biosimilar infliximab product in the United States until after September 15, 2015, the date the '715 patent expired.

2. All claims and defenses pending between the parties related to alleged infringement of the '715 patent under 35 U.S.C. § 271(e)(2)(C)(i) are dismissed as moot, and that dismissal is with prejudice only with respect to all claims and defenses related to the '715 patent and Defendants' proposed infliximab biosimilar products the subject of aBLA No.

125544.

3. All claims and defenses pending between the parties related to alleged infringement of the '056 patent under 35 U.S.C. § 271(e)(2)(C)(ii) are dismissed, and that dismissal is with prejudice only with respect to all claims and defenses related to the cell growth media described in the Cell Growth Media Spreadsheet.

Dated: September 28, 2015

/s/ Andrea L. Martin
BURNS & LEVINSON LLP

Dated: September 28, 2015

/s/ Alison C. Casey
NUTTER MCCLENNEN & FISH LLP

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CERTIFICATE OF SERVICE

I hereby certify that on September 28, 2015, a copy of the foregoing document was filed through the electronic filing system and served electronically to the registered participants as identified on the Notice of Electronic Filing.

/s/ Alison C. Casey

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